SEP 2 8 2000

K002387

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
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P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: August 3, 2000

TRADE OR PROPRIETARY NAME: Comfort Control™ Syringe System

CLASSIFICATION NAME: Cartridge syringe 872.6770

PREDICATE DEVICES: CCS Computer Controlled Syringe K983105

DEVICE DESCRIPTION:

The Comfort Control™ Syringe System is a partially automated, mechanized system intended for injection of anesthetics in dental procedures. The system is comprised of an electronic control unit, a handheld motor driven syringe (the "handpiece"), and a single-use cartridge sheath. All operating displays and the majority of the operator controls are located on the front panel of the control unit. The system is sold in only one configuration; there are no options. This system has no provisions for electronic communication with external devices.

INTENDED USE:

The device is indicated for the injection of local anesthetics for anesthesia administered prior to, or in conjunction with, dental procedures.

TECHNOLOGICAL CHARACTERISTICS:

Drive method - The Device and Predicate Device both use a stepper motor with integral leadscrew to produce slow, controlled, linear motion driving the plunger of the anesthetic cartridge. The Device and Predicate device both operate the stepper motor in the commonly used "open loop" mode, utilizing motor step counting rather than an additional encoder.

Displays - The Device and Predicate Device both use liquid crystal displays (LCD's) to display rate and time information, and light emitting diodes (LED's) for status indications.

Power - The Device and Predicate Device both use an external power supply to convert AC supply voltage to the low-voltage (12 volt) DC used in the control unit and handpiece.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2000

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K002387
Trade Name: Comfort Control Syringe System
Regulatory Class: II
Product Code: EJI
Dated: August 3, 2000
Received: August 4, 2000

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucente/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002387

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K002387

Device Name: **Comfort Control™ Syringe System**

Indications for Use:

The device is indicated for the injection of local anesthetics for anesthesia administered prior to, or in conjunction with, dental procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002387